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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,108	09/29/2000	Lynn Joens	M0-4890	2035
31846	7590	02/23/2004	EXAMINER	
INTERVET INC 405 STATE STREET PO BOX 318 MILLSBORO, DE 19966			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/677,108	JOENS, LYNN	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5,27-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5,27-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-10-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 10-30-2003 are acknowledged. Claims 5 and 27 have been amended. Claims 8-21 and 23-25 have been canceled. Claims 3-5, 27-29 and 31 are pending and currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 11-10-2003 is acknowledged. An initialed copy is attached hereto.

Objections Withdrawn

The objection to the specification for the improper use of trademarks is withdrawn in light of the amendment thereto.

Claim Objections Withdrawn

The objection to claim 27 for reciting material drawn to non-elected inventions is withdrawn in light of the amendment thereto.

Claim Objections Withdrawn

The new matter rejection of claims 3-5, 27-29 and 31 under 35 U.S.C. 112, first paragraph, is withdrawn in light of the amendment thereto.

The rejection of claims 3-5, 27-29 and 31 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising inactivated whole cell *L. intracellularis* (ATCC No. 55370) and whole cell lysates thereof, that induce the

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production of protective antibodies that react with *L. intracellularis* (ATCC No. 55370) antigen with a molecular weight of 21 kDa, 41 kDa, 43 kDa, 44 kDa, 60 kDa, 71 kDa or 115 kDa, does not reasonably provide enablement for any compositions comprising any *L. intracellularis* antigens other than inactivated *L. intracellularis* (ATCC No. 55370) and whole cell lysates thereof is withdrawn in light of the amendment thereto.

The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “protective antibodies” is withdrawn in light of the amendment thereto.

The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “*L. intracellularis* has all the **immunogenic characteristics** of ATCC deposit No. 55370” is withdrawn in light of the amendment thereto.

The rejection of claims 3-5, 27-29 and 31 under 35 U.S.C. 102(b) as being anticipated by Knittel et al. (WO 96/369629 – IDS-14) is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 3-5 and 27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Knittel et al. (WO 96/369629 – IDS-14) in view of Joens et al (U.S. Patent 5,610,059 - IDS-4) is maintained for reasons of record.

Applicant argues:

1. There is no expectation of success in producing a successful immunogenic with ATCC deposit No. 55370 as the art is inherently unpredictable.

Applicant's arguments have been fully considered and deemed unpersuasive.

The rejected claims are drawn to a an immunogenic composition comprising **inactivated *L. intracellularis*** strain deposited as ATCC deposit No. 55370 and optionally an **adjuvant** or an **inactivating agent** as well as a method of using said immunogenic composition to protect a mammal from the disease caused by *L. intracellularis*. Moreover, the *L. intracellularis* can be in the form of a whole cell or a whole cell lysate. It should be noted that the elected invention is **limited to whole cell culture** vaccines (immunogenic compositions). The ability to induce protective antibodies is an inherent property of the microorganism (vaccine composition) since cell preparations would comprise all the antigens of the *L. intracellularis*.

Knittel et al. disclose vaccine compositions comprising inactivated whole cell *L. intracellularis* or lysates thereof and an adjuvant (see page 17-18 and Example 6) and the use of said vaccines in swine. Knittel further disclose that said bacteria can be inactivated by the addition of formalin (see page 17, lines 30-33) and that the adjuvant used could be aluminum hydroxide (see page 18, lines 1-4). Knittel et al. differ from the instant invention in that they don't explicitly disclose the use the organism with the ATCC deposit No. 55370. Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L.*

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intracellularis is further disclosed to be inoculated into porcines in order to check its pathogenicity (see examples 1 and 2). Moreover, the isolated *L. intracellularis* disclosed by Joens et al. was deposited with ATCC with the deposit number 55370 (see column 8, lines 14-21 and claim 1). Additionally, Joens et al. disclose that said the *L. intracellularis* culture could be used to develop a "bacterin" using techniques known in the art such as heat treatment or chemical inactivation (see column 4, lines 6-16) said bacterin could be administered to porcines to "permit the pigs to mount an effective immune response against the agent (PPE)". Therefore it would have been obvious to one of skill in the art to use the antigen disclosed by Joens et al. (ATCC deposit No. 55730) in the vaccine compositions of Knittel et al. Moreover, it would have been equally obvious to use the resulting vaccine compositions to protect swine from diseases caused by *L. intracellularis* infection. Contrary to Applicant's assertion, the disclosure by Joens et al. that said bacterin (immunogen) could be administered to pigs to "permit the pigs to mount an effective immune response against the agent (PPE) would provide one of skill in the art not only of a reasonable expectation of success but a motivation to use the disclosed antigen (ATCC No. 55730) as a vaccine. Therefore, for the reasons set forth above, the combination of the disclosures by Knittel et al. and Joens et al. renders all the rejected claims obvious.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 28 recites the limitation "*L. intracellularis* antigen" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 29 recites the limitation "*L. intracellularis* antigen" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

L. F. S.
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
February 11, 2004